PSJ3

Exhibit 212A

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INTERNET PHARMACY DATA

Meeting With
Cardinal Health, Inc.
DEA Headquarters
August 22, 2005

CAH_MDL_PRIORPROD_DEA07_01178736

INTERNET PHARMACY DATA

Meeting With
Cardinal Health, Inc.
DEA Headquarters
August 22, 2005

Internet Pharmacies

- Domestic Based
  - Related to an existing pharmacy
    - Walk in patients with prescriptions
    - Some legitimate some not
  - Unrelated to brick and mortar pharmacy
    - No local patients or doctors
    - No walk-in business
- Foreign based

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Involved With Internet Pharmacies

- Doctors
- Pharmacies
- Distributors

- Internet Service Providers
- Credit Card Companies
- Delivery Services
- Internet Pharmacy Facilitators

ISSUES TO CONSIDER

- Frequency of Orders
- Size of Orders
- Range of Products Purchased
- Payment Method
- Pharmacy Location
- % Controlled vs. % Non-Controlled
- Customer pick up at distributor

3

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DEA DISTRIBUTOR REGISTRATIONS

- Title 21 United States Code, Section 823
  - Is the registration in the public interest?
    - Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical channels

Supreme Court Case

- Direct Sales Co, Inc. v. United States (1943)
  - Mail order sales to doctor
  - Most sales were Morphine
  - Increase in quantities purchased
  - Business practices attracted customers who were violating the law
  - Drugs have inherent susceptibility to harmful and illegal use

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EZ RX, LLC

- 69 FR 63,178 (2004)
  - Revocation of DEA Registration
  - Immediate Suspension of DEA Registration
    - 300,000 dosage units in three months
    - Phentermine, Phendimetrazine, Ambien

RX Network of South Florida, LLC

- 69 FR 62,093 (2004)
  - Revocation of DEA Registration
  - Immediate Suspension of DEA Registration
    - 19,300,000 dosage units of various controlled substances
    - Based on Internet Questionnaires
  - Not in the course of professional practice

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Supreme Court Case

- United States v. Moore
  423 U.S. 122 (1975)
  - Usual course of professional practice
    - Patient with a Medical Complaint
    - History
    - Physical Examination
    - Nexus Between Complaint/History/Exam and Drug Prescribed

DEA Internet Policy

- ~~68 FR 21,181 (2001)~~
- Prescriptions can only be issued by a doctor acting in the usual course of professional practice
- Prescription not issued in the usual course of professional practice is not valid
- An Internet questionnaire alone is not sufficient to legally prescribe controlled substances

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VIPPS

- National Association of Boards of Pharmacy
  - Licensed, legitimate, Inspection
  - Verified Internet Pharmacy Practice Sites
  - 14 VIPPS Approved Pharmacies as of 06-27-2005
  - www.nabp.net/vipps/consumer/faq.asp

American Medical Association

- H-120.949 Guidance for Physicians on Internet Prescribing
  - valid patient-physician relationship, includes, but not limited to:
    - History and physical exam
    - Dialogue with patient
    - Follow up to assess outcome
    - Maintain medical record
    - Include electronic prescription in patient's medical record

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Example #2

- Retail Pharmacy
  - Location of store
  - Only Hydrocodone and Alprazolam
  - Very large quantities
  - FedEx boxes for delivery

ANOTHER PHARMACY

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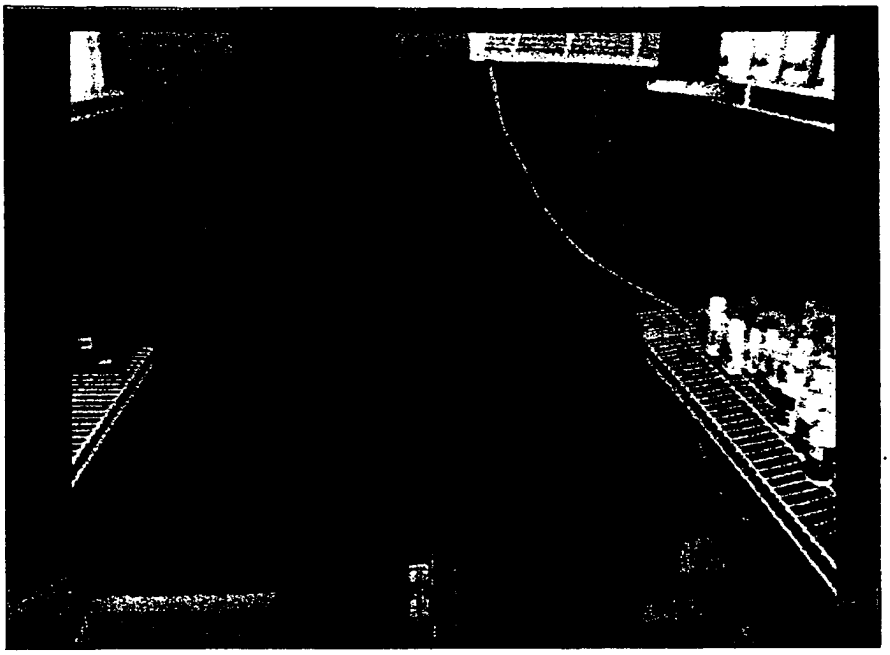

Example #3

- Advised Distributor they are an Internet Pharmacy
- No VIPPS approval
- Frequent Large Orders
- Hydrocodone and Benzodiazepines
- 99% controlled substances
- No established business credit

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AN INTERNET PHARMACY

SUMMARY

- Prescriptions not written in the usual course of professional practice are not valid
- Drugs dispensed pursuant to invalid prescriptions are not for legitimate medical purpose, the drugs are diverted
- Not limited to Internet pharamcies

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SUMMARY

- A pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor
- The DEA registration of the distributor could be revoked under public interest grounds

SUMMARY

- Any Distributor who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately
- DEA cannot guarantee that past failure to maintain effective controls against diversion will not result in action against a distributor

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SUMMARY

- DEA will:
  - Meet with other distributors involved in distributing to Internet pharmacies
  - Provide this information to your employees at your request
  - Meet with Industry groups or associations to discuss issue if requested

Contact Information

Michael Mapes
Chief, E-Commerce Section
703-653-2048

Kyle Wright
Chief, E-Commerce Operations Unit
703-653-2103

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U.S. Code as of: 01/06/03

Section 823. Registration requirements

Related Res

Health Law

Department of J Human Se Directo

Department o Directo

Agriculture D

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent

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with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting

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research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or

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detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

(iii) In any case in which the practitioner is not in a group practice, the total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number.

(iv) In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 262 of title 42, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f) of this section.

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f) of this section.

(ii) Upon receiving a notification under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f) of this section. The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the

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Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term ''group practice'' has the meaning given such term in section 1395nn(h)(4) of title 42.

(ii) The term ''qualifying physician'' means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

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(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.

(I) During the 3-year period beginning on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs, to patients for maintenance or detoxification treatment in accordance with this

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paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug. (FOOTNOTE 1)

(FOOTNOTE 1) So in original. Probably should be ''combinations of drugs.''.

(J)(i) This paragraph takes effect the date referred to in subparagraph (I), and remains in effect thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on October 17, 2000, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being dispensed or possessed in violation of this chapter; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that this paragraph should not remain in effect, this paragraph ceases to be in effect 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under section 802(39)(A)(iv) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider -

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

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(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

Previous [Notes] Next

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business on June 13, 2001. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436.

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

LIST OF SUBJECTS: Chile, tariffs, and imports.

By order of the Commission.
Issued: April 24, 2001.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–10527 Filed 4–26–01; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA–191N]

Dispensing and Purchasing Controlled Substances over the Internet

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Guidance.

SUMMARY: This notice is intended to provide guidance to prescribers, pharmacists, law enforcement authorities, regulatory authorities, and the public concerning the application of current laws and regulations as they relate to the use of the Internet for dispensing, purchasing, or importing controlled substances. This guidance document explains when controlled substances can be legally purchased from U.S.-based Internet sites. This notice clarifies that consumers must have valid prescriptions to obtain controlled substances legally and that consumers cannot legally purchase controlled substances from foreign supplier Internet sites and have them shipped to the U.S, unless the consumers are registered with DEA as controlled substances importers and are in compliance with all DEA requirements.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Why is This Notice Necessary?

With the advent of Internet pharmacies, DEA registrants and the public have asked how these Internet pharmacies fit into the requirements that currently exist for the prescribing and dispensing of controlled substances. DEA is issuing this notice to provide guidance to prescribers, pharmacists, law enforcement authorities, regulatory authorities, and the public about the application of current laws and regulations to the use of the Internet for prescribing, dispensing, purchasing, or importing controlled substances.

This document is in the format of questions and answers. The first section provides the context for this notice. The next two sections address issues that apply to DEA registrants and consumers.

General Questions

What are Controlled Substances?

Most drugs that require a prescription from a doctor are not controlled substances. The Controlled Substances Act and its implementing regulations, however, assign certain substances to one of five "schedules." These substances are placed in a schedule based on their potential for abuse, which may lead to physical or psychological dependency. Schedule I substances have no accepted medical use for treatment in the United States and are not available by prescription. Schedule II through V substances have accepted medical use and varying potentials for abuse and dependency. Practitioners (*e.g.*, doctors, dentists, veterinarians, physician assistants, advance practice nurses) who are licensed by a State and registered with DEA may prescribe these substances. Controlled substances include narcotics (pain relievers), stimulants, depressants, hallucinogens, and anabolic steroids. A complete list of controlled substances can be found in Title 21 of the Code of Federal Regulations (CFR) part 1308. Examples of controlled substances are shown below.

Schedule	Example of controlled substances
Schedule I	Heroin, marijuana, mescaline, methcathinone,
Schedule II	Amphetamine, codeine, fentanyl, Hydromorphone, meperidine, methadone, Methylphenidate (Ritalin), morphine, oxycodone, pentobarbital, phencyclidine (PCP), secobarbital
Schedule III	Anabolic steroids, phendimetrazine, and products that contain small quantities of certain schedule II controlled substances, such as codeine, in combination with noncontrolled ingredients, such as aspirin.
Schedule IV	Alprazolam (Xanax), chlordiazepoxide (Librium), diazepam (Valium), lorazepam (Ativan), phenobarbital, phentermine
Schedule V	Buprenorphine and many cough Preparations that contain a limited amount of codeine

What are the Basic Requirements for Prescribing, Dispensing, and Importing Controlled Substances?

Only practitioners acting in the usual course of their professional practice may prescribe controlled substances. These practitioners must be registered with DEA and licensed to prescribe controlled substances by the State(s) in which they operate. Pharmacies filling prescriptions for controlled substances must also be registered with DEA and licensed to dispense controlled substances by the State(s) in which they operate. A prescription not issued in the usual course of professional practice or not for legitimate and authorized research is not considered valid. Both the practitioner and the pharmacy have a responsibility to ensure that only legitimate prescriptions are written and filled.

Pharmacists must receive written and manually signed prescriptions for Schedule II substances. They may receive oral or faxed prescriptions for Schedules III–V substances provided they confirm the legitimacy of the prescription and the practitioner. Prescriptions for Schedule II substances may not be refilled. Prescriptions for Schedules III–V controlled substances may be refilled five times, but no prescription may be filled or refilled more than six months after the date on which the prescription was issued. Only those people who are registered with DEA as importers and who are in compliance with DEA requirements may have controlled substances shipped into the customs territory or jurisdiction of the U.S. from a foreign country.

DEA regulations covering prescriptions can be found in Title 21 of the Code of Federal Regulations, part 1306; rules on importation are found in 21 CFR 1312.

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Why are Internet Sales an Issue?

The Internet is primarily a communications tool that can be used to facilitate any type of business. On-line pharmacies are currently providing access to a full range of pharmaceuticals, including prescription drugs and controlled substances. Many people view the Internet as changing the way in which business is conducted. For controlled substances, however, the Controlled Substances Act and DEA's regulations continue to determine when and how these substances may be obtained. Internet sales must be in accordance with these requirements.

DEA rules affect how controlled substances may be ordered from an Internet pharmacy and the conditions under which such orders are legal. DEA is currently working on a revision to its regulations that will define the conditions under which prescribers may electronically sign and transmit to any pharmacy (retail, mail order, or Internet) prescriptions for controlled substances. Until these revisions are complete, however, use of the Internet for dispensing controlled substances is governed by existing DEA rules, described above.

DEA is issuing this notice to answer questions that legitimate pharmacies and practitioners have about using the Internet as part of their business. DEA is also aware that some Internet sites are engaged in the illegal sale of controlled substances. Consumers may be illegally purchasing controlled substances from these Internet sites without realizing that they are committing a crime. This notice provides information for consumers to help them understand when they may legally purchase controlled substances.

DEA Registrant Questions About Internet Pharmacies

Must my Internet Pharmacy be Registered with DEA?

The actual physical location of the pharmacy which purchases, stores and dispenses controlled substances pursuant to prescription orders processed by the Internet site must be registered with DEA. The web site itself would not require a separate registration unless it is the same physical location, since the web site does not store or dispense controlled substances. For example, some Internet pharmacies maintain a central pharmacy warehouse site and offices where prescriptions are verified and substances shipped; this location must be registered with DEA as a retail pharmacy. Other Internet sites allow patients to pick up their prescriptions for controlled substances from a local pharmacy; these local pharmacies must be registered with DEA. In this case, the Internet "pharmacy" has no obligations under DEA regulations because the responsibility for assuring compliance with DEA regulations rests with the actual pharmacy where the controlled substances are dispensed.

Your pharmacy must have a license from the State in which the controlled substances are stored and dispensed and, in most instances, from any state in which you plan to conduct business with customers. You should also be aware that many States require licenses for the web site itself since these sites often provide services like patient counseling.

Does the Label on a Prescription I Fill Indicate the Internet Pharmacy or the Registered Location that Filled the Prescription?

The label must list the registered location that dispensed the controlled substance.

Does Being an Internet Pharmacy Change my Responsibilities Under DEA Regulations?

No, you are still authorized to sell controlled substances only when there is a valid prescription from a DEA-registered practitioner who issued the prescription in the usual course of his or her professional practice.

Is it Possible for my Internet Pharmacy to Fill Prescriptions for Schedule II Substances?

You may fill valid prescriptions for Schedule II substances if the patient or prescriber provides you with the signed original prescriptions prior to dispensing. Practically, it is unlikely that most patients will want to wait the time required for such a transaction.

Is it Possible for my Internet Pharmacy to Fill Prescriptions for Schedule III–V Substances?

You may receive an original signed prescription or a facsimile of the original signed prescription, or an oral prescription, where allowed, which you verify and immediately reduce to writing. You have the responsibility to ensure the legitimacy of the prescription and the prescriber. At this time, DEA does not permit a prescription received via the Internet to be filled. If you receive prescription information transmitted via the Internet, you must contact the prescriber via telephone and receive an oral prescription for the controlled substance, including the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner (21 CFR 1306.05(a)). You must immediately reduce this oral prescription to writing (21 CFR 1306.21(a)).

Does DEA Intend to Allow Electronic Transmission of Prescriptions in the Future?

DEA is currently engaged in a project to determine the requirements for secure electronic transmission of all controlled substance prescriptions between the practitioner and the pharmacy. When completed, these requirements will automatically certify the authenticity of the prescriber, protect the content of the prescription from alteration, and bind the digital signature on the prescription to the actual prescriber and no one else. These requirements will be subject to rulemaking, and you will have an opportunity to comment on them before they are finalized. You can find more information on this project on the DEA web site at http://www.deadiversion.usdoj.gov/ecomm/index.html.

Can Patients Request a Refill of a Controlled Substance Prescription From my Pharmacy by Sending me an email Instead of Calling me on the Telephone?

Yes, the Internet can be used to facilitate communication between you and your patient when your patient is requesting a permissible refill of an existing Schedule III–V controlled substance prescription.

Some Internet Pharmacies have Doctors who Prescribe Substances Based on an on-line Questionnaire. Is this Legal?

Federal law requires that "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" (21 CFR 1306.04(a)). Every state separately imposes the same requirement under its laws. Under Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship.

For purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate doctor/patient relationship has been established:

- A patient has a medical complaint;
- A medical history has been taken;
- A physical examination has been performed; and

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• Some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.

Completing a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship. A consumer can more easily provide false information in a questionnaire than in a face-to-face meeting with a doctor. It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate doctor/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone. However, as discussed later in this document, this circumstance is not intended to limit the ability of practitioners to engage in telemedicine. For purposes of this guidance document, telemedicine refers to the provision of health care using telecommunication networks to transmit and receive information including voice communications, images, and patient records.

Some sites recommend to the patient that they not take a new drug before they have a complete physical performed by a doctor. These sites then ask the patient to waive the requirement for a physical and to agree to have a physical before taking the drug they purchase via the Internet. An after-the-fact physical does not take the place of establishing a doctor/patient relationship. The physical exam should take place before the prescription is written. These types of activities by Internet pharmacies can subject the operators of the Internet site and any pharmacies or doctors who participate in the activity to criminal, civil, or administrative actions. For DEA registrants administrative action may include the loss of their DEA registration. Additionally, providing false material information to obtain controlled substances could be considered obtaining a controlled substance by fraud and deceit, which is subject to Federal and State penalties.

I am a Practitioner who is Considering Starting an Internet Practice. Can I use the Internet to Facilitate the Prescribing of Controlled Substances?

You may use the Internet to provide information and to communicate with the patient, but it cannot be the sole basis for authorizing prescriptions. If a doctor/patient relationship exists, you can use the Internet to communicate with patients. Where a doctor/patient relationship exists, you may use the Internet to receive requests for treatment. DEA cautions, however, that such requests for treatment should be logical based on your knowledge of the patient's medical history and the medical complaint. You may also use the Internet to receive requests for refills of prescriptions from patients.

I am a Physician. Does the need for a Physical Exam Mean that I Cannot Engage in Telemedicine and Prescribe Controlled Substances?

No, DEA does not intend to limit the ability of doctors to engage in telemedicine. If the patient cannot travel to your office, but you supervise an exam given by a nurse or other professional, you can then prescribe the needed medications based on the results, to the extent that State law allows. In this case, your decision on the appropriateness of the medication is based on facts (symptoms, blood pressure, etc.) that have been verified by a qualified third party and observed by you electronically.

I have Read in the Controlled Substances Act (CSA) that it is a Violation of the law to use a Communications Facility to Facilitate the Illegal sale of a Controlled Substance. Does this Apply to the use of the Internet to Obtain Pharmaceutical Controlled Substances?

Yes, Title 21, United States Code, section 843(b) defines a communication facility as "any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication." Anyone who uses the Internet to facilitate the illegal sale of a controlled substance would be in violation of 21 U.S.C. 843(b), which is punishable by a term of imprisonment of not more than four years and a fine of not more than $30,000. This provision could apply to owners of Internet sites, prescribers, pharmacists, and patients.

Questions for Consumers

Are Internet Pharmacy Sites Legitimate?

Many Internet pharmacy sites are legitimate. These Internet pharmacy sites may vary in the services they provide, but they may fill a prescription for a controlled substance which was issued to you by an authorized practitioner for a legitimate medical purpose. They should confirm the legitimacy of the prescription for a Schedule III–V controlled substance before filling it by contacting the prescriber. They are not authorized to fill a prescription for a Schedule II controlled substance unless they have first received the original signed prescription.

Some Internet sites for pharmacies advertise local pharmacies and usually list the name, address, and telephone number of the local pharmacy closest to you. Many of these sites provide a great deal of information concerning specific diseases or medical conditions, and drug information. Many Internet sites operated by local pharmacies or mail order pharmacies serve as a communication link so that you can request refills of prescriptions, check the status of your prescription, or ask the pharmacist a question. These are appropriate uses of the Internet by pharmacies.

Some sites simply provide information about specific drugs and medical conditions. After obtaining some general information from you, this type of "Internet Pharmacy" will refer you to a specific local pharmacy or a mail order pharmacy to have the prescription that you obtained from your physician filled. These are appropriate uses of the Internet by pharmacies.

Are There Internet Pharmacy Sites That are Not Legitimate?

Some Internet pharmacy sites do not require that you have a prescription from your doctor. These "Internet Pharmacies" require the customer to complete a medical questionnaire. This type of site advises that the information will be reviewed by a doctor, and the drug will be prescribed and sent to you, if appropriate. The medical questionnaire often has most of the questions set so that if the default answers are not changed, the questions are answered in an appropriate manner to obtain the desired drug. Questionnaire sites often require that the customer waive certain rights. This type of pharmacy usually does not name the doctor who will be reviewing the medical questionnaire or provide any information about the qualifications of the doctor. These sites operate in a manner that is not consistent with state laws regarding standards of medical practice and may be engaging in illegal sales of controlled substances (see discussion above).

Some Internet Pharmacy sites are operating in a foreign country and often do not require any prescription before sending controlled substances to you. These sites often advise that there have been changes to the U.S. law that authorize the customer to import a controlled substance into the United States without benefit of a prescription. These types of sites may be engaging in

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illegal sales of controlled substances (see discussion below).

Is it Legal to Buy Controlled Substances From Foreign Internet Sites and Have Them Shipped to the U.S.?

No, having controlled substances shipped to the U.S. is illegal unless you are registered with DEA as an importer and you are in compliance with 21 U.S.C. 952, 953, and 954 and 21 CFR part 1312. Some foreign Internet sites claim they can legally sell these controlled substances; other sites, knowing that such shipments are illegal, advise consumers of ways to avoid having the packages seized by U.S. Customs. The Controlled Substances Act prohibits any person from importing into the customs territory of the U.S. any controlled substance or List I chemical (21 U.S.C. 971 and 21 CFR part 1313) unless that person maintains a valid, current authorization to import such substances or chemicals (21 U.S.C. 957(a)). DEA regulations further state:

"No person shall import or cause to be imported any controlled substance * * * unless and until such person is properly registered under the Act (or exempt from registration) and the Administrator has issued him a permit o do so pursuant to § 1312.13. * * *" (21 CFR 1312.11(a))

Illegal importation of controlled substances is a felony that may result in imprisonment and fines (21 U.S.C. 960).

The CSA Provides a Personal Use Exemption for Controlled Substances Purchased Abroad. Does the Exemption Apply to Controlled Substances Bought from a Foreign Internet Site?

The Controlled Substances Act and DEA regulations allow you a personal use exemption to bring a limited quantity of controlled substances into the U.S. for your use only when you bring the controlled substances across the U.S. border in your possession (21 U.S.C. 956, 21 CFR 1301.26). It does not apply to controlled substances being shipped into the U.S. Purchasing controlled substances on the Internet and having them shipped to you in the U.S. is not permitted by the personal use exemption. Such purchases and shipments would be considered "imports" of the controlled substance even if the substance is for your personal use. Unless you are registered as an importer and in compliance with the requirements, such shipments are illegal and subject to seizure.

Does it Make a Difference if I Have a Prescription from a U.S. Doctor for Controlled Substances That I Buy From a Foreign Internet Site?

No, the law remains the same. Unless you are registered with DEA as an importer and are in compliance with DEA's requirements, you may not have controlled substances shipped to you in the U.S. from another country.

What are the Things to Consider in Selecting an Internet Pharmacy?

An "Internet Pharmacy" site should provide a physical address for the pharmacy, in addition to the Internet address, and a telephone number for the pharmacy.

Some indicators that the "Internet Pharmacy" may not be legitimate and should not be used as a source for controlled substances are the following:

- The site is not a participant in any insurance plan and requires that all payments be made with a credit card.
- The site requires that you waive some rights before they send you the drugs.
- The site advises you about the law and why it is permissible for you to obtain pharmaceutical controlled substances from foreign countries via the Internet.
- The site does not ask the name, address, or phone number of your current physician.
- The site advises you to have the drugs sent to post office boxes or other locations to avoid detection by U.S. authorities.

I Have Seen a VIPPS Seal on Some Internet Pharmacy Sites. What Does This Mean?

The National Association of Boards of Pharmacy (NABP) has developed a voluntary program called the Verified Internet Pharmacy Practice Sites (VIPPS). The NABP has begun issuing a "seal of approval" to Internet pharmacies that meet standards regarding State licensing and DEA registration. To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their State and each State to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. The NABP also provides information on whether a pharmacy is licensed and in good standing (see *http://www.nabp.net*).

Are the Rules Different for "Life Style" Drugs?

Some people have applied the phrase "life style drugs" to certain medications, such as Viagra, weight control medications, and tranquilizers. Many of the so-called life style drugs are not controlled substances. If a "life style" drug is a controlled substance, however, it is still subject to all regulations for controlled substances. You must obtain a prescription from a DEA registered prescriber and have it filled by a DEA registered pharmacy.

I Have a Complaint About an "Internet Pharmacy" Site on the Internet That Appears to be Illegally Selling Drugs. Where Should I Send the Complaint?

If the complaint involves a pharmaceutical controlled substance, contact the DEA, Office of Diversion Control, Drug Operations Section, Washington, DC 20537, telephone (202) 307–7194 or your local DEA office (for a list of contacts, see *http://www.dea.gov/agency/domestic.htm.*)

If the complaint involves any pharmaceutical drug other than a controlled substance, contact the U.S. Food and Drug Administration, HFC–230, 5600 Fishers Lane, Rockville, MD 20857, or file a report on the FDA's web site at *http://www.fda.gov/oc/buyonline/buyonlineform.htm.*

If the complaint involves a pharmacist or a physician, you may contact the State Board of Pharmacy or the State Board of Medicine where the doctor or pharmacist is located.

Additionally, you may wish to view other sites on the Internet that are for registering complaints such as the NABP (*http://www.nabp.net*).

Dated: March 19, 2001.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF LABOR

Employment Standards Administration Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study

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In a July 13, 2004 news release, the Food and Drug Administration made the following statement:

"The Agency believes that *consumers* should look for participation in this type of certification program [VIPPS®] as one method to help *minimize the risks* of getting bad quality drugs from disreputable sources."

Verified Internet Pharmacy Practice Sites™ (VIPPS®)
Most Frequently Asked Questions

VIPPS® PROGRAM

What is the VIPPS Program?

The Verified Internet Pharmacy Practice Sites™ (VIPPS®) program and its accompanying VIPPS seal of approval identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection.

How does NABP verify the sites?

Internet-based pharmacy practice sites wishing to become VIPPS-certified submit a detailed application to NABP, which includes the pharmacy's policies and procedures addressing the VIPPS criteria. Licensure information is verified with applicable state boards of pharmacy. The VIPPS team reviews the application, policies, and applicant's Web site, and performs an on-site inspection of the pharmacy's facilities. Once the policies and procedures as well as the operations of the pharmacy appear to meet the intent of the VIPPS criteria, permission to display the VIPPS Seal is granted and the verified information about the pharmacy is posted on the VIPPS Web site. Clicking on the VIPPS Seal links the user to the VIPPS Web site that then verifies that the Seal is indeed posted on a VIPPS-certified site. If so, the user is then shown pharmacy-specific information, including licensure information.

Does NABP regulate online pharmacies?

NABP does not regulate online pharmacies. Regulation of pharmacy practice, whether online or not, is primarily the jurisdiction of the state boards of pharmacy with some federal oversight. The VIPPS program is a voluntary certification program for which Internet pharmacy practice sites may apply. The value of the program to the patient and the Internet pharmacy is that it provides members of the public with a means to assure themselves that the Internet pharmacy they choose is a bona fide, fully licensed facility exercising competent Internet/interstate pharmacy practices.

When was the VIPPS program developed?

In 1999, NABP became aware of the need for this program when consumers contacted several state pharmacy boards to complain about illegal Internet prescribing and dispensing sites posing as legitimate pharmacies. The Association developed the VIPPS program in response to public and regulatory agency concerns regarding safety of Internet pharmacy practices in order to provide a means for the public to distinguish between legitimate and illegitimate online pharmacy practice sites.

Isn't the number of Internet sites far too large to monitor and control?

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No. NABP and the regulatory framework of state boards of pharmacy, federal agencies, and the medical community have been working together for several years now to achieve this goal.

Online Pharmacy Questions

How many online pharmacies are out there?

It is difficult, if not impossible, to answer this question accurately, but it is probably fewer than you would think. Illegitimate pharmacies (usually those that offer online prescribing) open and close on a daily basis. One company posing as a legitimate pharmacy may have many URLs or Web addresses, creating the impression that there is a greater number of Internet pharmacies than actually exists. In addition, pharmacies may only register with select search engines. If these search engines are not utilized when performing a search then all pharmacies may not be counted.

How many prescribing sites are out there?

The number of prescribing sites, using patient questionnaires and fee-based cyberspace consultations, as well as sites that sell prescription medications and controlled substances without requiring a "consult," is difficult to estimate. NABP's research indicates that the number of such rogue operators is less than the number of legitimate online dispensing pharmacies.

What's wrong with using a prescribing site to get Viagra® and Xenical®? I don't have to see a doctor and can obtain the medicine with increased privacy and confidentiality; and it's cheaper.

First, the Food and Drug Administration (FDA) restricts the distribution of certain drugs to a prescription-only basis because in certain medical situations they can be dangerous if not taken with ongoing medical consultation. Most regulatory authorities and professional organizations regard online prescribing to be unprofessional, and in some states it is illegal, unless it is done pursuant to a valid, ongoing patient-prescriber relationship that has included an in-person physical examination. Completing only an online questionnaire does not establish a valid patient-prescriber relationship. Moreover, without a physical examination you could receive inappropriate medication and worsen an underlying, undiagnosed, serious medical condition.

As for increased privacy and confidentiality, evidence appears to indicate that illegitimate prescribing sites frequently sell their customer lists to other illegitimate online pharmacy operators and owners of Internet scam and pornography sites. By buying drugs from an illegitimate site you may be designating yourself as someone who is a good target for rip-off schemes.

Frequently, deceived consumers notify us of non-receipt of medications they ordered, and/or credit card charges that illegitimately operating pharmacies refuse to remove. Many also complain that they are unable to contact the pharmacies: phone lines are disconnected or no one answers.

Can I get really cheap prices from pharmacies outside the US?

First, the FDA generally prohibits the importation of foreign-made versions of prescription medications that are commercially available in the US. The safety and efficacy of these medications cannot be guaranteed. Many countries' drug research and control programs are not as safety oriented as those in the U.S. Though some of the drugs advertised by foreign sites may be manufactured by the same name brand international drug manufacturer as you are used to, they usually are not manufactured in FDA inspected facilities that have met FDA standards. Further, sometimes the medications have been subjected to storage conditions that compromised their potency or safety.

Can I get cheap prices from legitimate online pharmacies?

Yes, and more. One of the great benefits to shopping online to fill your prescriptions is the ease with which you can comparison shop. Many pharmacies offer price

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comparisons between their charge and that of other legitimate pharmacies. This is one way to stretch your health care dollar. Many online pharmacies accept prescription benefit insurance coverage as well. In addition, legitimate online pharmacies often offer valuable health care information in a searchable format. VIPPS-certified pharmacies are required to offer their customers free phone consultation with a pharmacist, and many offer free ask-a-pharmacist e-mail service as well.

What are the main advantages of ordering medications online?

Convenience is a major advantage that online pharmacies provide over some of their pharmacy competitors. Consumers' ability to order and receive medications without leaving their home is a tremendous time-saver. Often, drug information and price information may be accessed via the pharmacy's Web site, or this information may be requested via e-mail so the consumer does not have to wait on the phone for an answer or travel to the pharmacy to ask for this information in person.

In addition, online pharmacies may provide more privacy than traditional brick-and-mortar pharmacies. Consumers who are too embarrassed to purchase certain medications or health care products from the local pharmacy may find greater anonymity by ordering these products from an e-pharmacy where staff may not be able to put a "face to a name."

Laws/Regulations

Who regulates online pharmacies?

The state boards of pharmacy have primary responsibility for regulation of online pharmacies. Regulatory authority is mainly exercised by the state board of pharmacy of the state in which the pharmacy is physically located. In addition, most states protect their citizens by licensing "out-of-state pharmacies" that ship medications to patients in their jurisdictions. The same regulations that apply to traditional brick-and-mortar and mail-order pharmacies typically apply to online pharmacies. Federal agencies, such as the FDA and Drug Enforcement Administration (DEA), are also partners with the state boards of pharmacy in this regulatory process. The FDA, however, mainly regulates foreign-based sites and practitioners.

How do I set-up an online pharmacy?

When pharmacists are thinking about setting up an online pharmacy, we encourage them to do their homework and work in conjunction with the state boards of pharmacy. The VIPPS criteria may serve as a solid guideline when an organization plans to expand into interstate/Internet pharmacy practice and seeks to address issues of quality, verifiable relationships, regulatory compliance, and good pharmacy practices.

How does NABP work with government agencies that regulate online pharmacies?

NABP has strong working relationships with the state boards of pharmacy and the federal agencies. Inspector training programs and the VIPPS "Report a Suspicious Site" programs are examples of ways in which NABP helps regulatory agencies monitor and investigate illegitimate pharmacy Web sites.

How are international online sites regulated?

As mentioned earlier, online sites located outside the United States pose the greatest challenges for state and federal regulators. Cooperation with other nations and their regulatory agencies has been and continues to be the key to regulating online international pharmacy sites. NABP is working with a number of international regulatory agencies to establish VIPPS programs for their online pharmacies.

What organization can I contact regarding regulations and online pharmacies?

Your first contact should be the local state board of pharmacy . You may also subscribe to NABPLAW®, NABP's state pharmacy law and rules database, which allows users to research subjects one state at a time or across all 50 states. Annual subscriptions include two updates to assure users' access to the most accurate information possible.

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For more information contact NABP's Publications Desk, or e-mail NABP at custserv@nabp.net.

What if I believe an online pharmacy has dispensed the wrong medication or labeled the medication incorrectly?

Please report these incidents to your local state board of pharmacy as well as the board of pharmacy in the state where the pharmacy is located. You should also contact the pharmacy that mistakenly dispensed the medication. VIPPS pharmacies are required to document, track, and analyze these types of incidents to determine what went wrong and to prevent recurrences.

What are the signs of a suspiciously operating pharmacy?

First, e-pharmacies are suspect if they dispense prescription medications without requiring the consumer to mail in a prescription, and if they dispense prescription medications and do not contact the patient's prescriber to obtain a valid verbal prescription. Further, online pharmacies are suspect if they dispense prescription medications solely based upon the consumer completing an online questionnaire without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination. State boards of pharmacy, boards of medicine, the FDA, as well as the AMA, condemn this practice and consider it to be unprofessional.

Second, online pharmacies should have a toll-free phone number as well as a street address posted on their site. If the pharmacy merely has an e-mail feature, so that the sole means of communication between the consumer and the pharmacy is via e-mail, this is a suspect site.

Third, legitimate sites allow consumers to contact pharmacists if they have questions about their medications. If a site does not advertise the availability of pharmacists for medication consultation, it should be avoided.

Many suspiciously operating e-pharmacies have limited numbers of medications that they sell, particularly "lifestyle" medications that treat such conditions and diseases as impotence, obesity, herpes, pain, and acne. Although pharmacies may not sell every medication available in the US, those online pharmacies solely selling lifestyle medications may not be operating legitimately.

What if I believe that an online pharmacy may be operating suspiciously?

Please report suspiciously operating pharmacies to NABP by using the "Report-a-Site" feature in the VIPPS section of our Web site. You may do so anonymously. We also encourage you to report such sites to your local state board of pharmacy, especially if you or a loved one has been harmed. NABP forwards information regarding suspiciously operating sites to the most appropriate regulatory authorities.

What organization covers the security of patient information for online pharmacies?

Security, confidentiality, and privacy are among the chief concerns of patients and health care professionals regarding online pharmacy services. State and federal laws such as the Health Insurance Portability and Accountability Act (HIPAA) protect patient identifiable information. VIPPS and other voluntary certification programs require participating organizations to adhere to and post their privacy policies. In addition, NABP has published guidelines regarding the confidentiality of patient health care information. Please contact NABP, 847/391-4406, for information about obtaining a copy of these guidelines.

Prescriptions/Prescribers

Can a prescription be faxed to the online pharmacy, or does the pharmacy need the original prescription? Does the online pharmacy verify the prescription with the prescriber?

Generally state laws require faxed prescriptions to be received directly from the

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prescriber (not the patient) to be valid. Online sites that do not protect the integrity of the original prescription, or that do not verify the authenticity of suspect prescriptions may be in violation of the law. In addition, VIPPS-certified pharmacies must have policies and procedures in place that address these issues. Before you entrust your health to anyone online, look for the VIPPS Seal, and click to verify.

Disclaimer

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In a **July 13, 2004** news release, the Food and Drug Administration made the following statement:

"The Agency believes that *consumers* should look for participation in this type of certification program [VIPPS®] as one method to help *minimize the risks* of getting bad quality drugs from disreputable sources."

VIPPS® Certification Process

The VIPPS certification process begins when the applicant submits a VIPPS application form with application fees to NABP. (See Application form and Instructions)

- Upon receipt of the application form and supporting documentation, NABP staff will:
  - Verify all necessary state pharmacy licenses are in good standing
  - Verify the Pharmacist-in-Charge licenses are in good standing
  - Evaluate the submitted support documents against the Interpretive Guide to the VIPPS Criteria
- Notify the applicant if discrepancies arise or clarification is needed.
- After review of the dcoumentation, staff schedules an on-site inspection of the pharmacy to evaluate the applicant's operations, policies and staff for compliance with the VIPPS criteria.
  Inspections may be required:
  - Upon notice of a complaint against a VIPPS certified pharmacy
  - At the request of a participant in the course of VIPPS certification suspension action.
  - Re-inspections of VIPPS-Certified pharmacies are required once every three years.
- Following review of the application materials, verification of submitted information and licensure, and inspection, a written report will be sent to the pharmacy. If the review is satisfactory the report will include:
  - a VIPPS Letter of Agreement to be signed by an authorized representative or agent of the entity with authority to bind the entity
  - an invoice for the first year participation fee.
- Upon receipt of the executed Letter of Agreement and fee, NABP releases a code to the applicant which allows access to a secure area of the VIPPS Web site where the applicant may retrieve and download their VIPPS hyperlink Seal and carry out other administrative functions. Guidelines for the use of the Seal are included in the Letter of Agreement.
- The VIPPS certification is renewable annually following an update of the registration information and re-verification of licensure status.

The entire process from initial application to award of the Seal should take one to two months depending on scheduling and timeliness and quality of the applicant's response.

VIPPS Certified Pharmacies receive:

- NABP/VIPPS hyperlink Seal to display on their Web site. Focus group studies have demonstrated the Seal's power of reassurance to prospective Internet pharmacy users for a number of reasons.

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- To those trusting their health and life to an unknown entity on the Internet, the NABP Seal represents the comfort afforded by a hundred-year heritage of dedication to protecting the public health through assisting state boards of pharmacy regulating pharmacy practices.
- The public can access comprehensive company information regarding each VIPPS pharmacy.
- Patients appreciate the clear, understandable, and professionally reviewed requirements, which allows them to judge the merit of certification for themselves.
- The certification requirements address their fears and concerns.

- Expanded Internet presence. NABP is committed to supply a network of connections from its Web site to government agencies. NABP is also working to establish referral links to its Web site from not-for-profit organizations and other pharmacy-related websites. Once in the VIPPS site, visitors may search the database for the Internet pharmacy of their choice.
- A comprehensive overview of their pharmacy operations and policies, with suggestions for improvements and streamlining of services.
- VIPPS Pharmacies also may find benefit from access to NABP resources and expertise in licensure, professional credentialing and regulatory compliance.

Disclaimer

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Consumer Menu

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Search for a Pharmacy

LIST OF PHARMACIES

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VIPPS Database Search Results

Your search yielded 13 pharmacy(s):

Detail	Web Business Name	Website Address
	accuratepharmacy.com	www.accuratepharmacy.com
	Anthem Prescription	www.anthemprescription.com
	Caremark.com	www.caremark.com
	DrugSource, Inc.	www.drugsourceinc.com
	drugstore.com	www.drugstore.com
	Familymeds.com	www.Familymeds.com
	HOOK SUPERX, Inc, dba CVS/pharmacy	www.cvs.com
	Medco Health Solutions, Inc.	www.medcohealth.com
	Omnicare, Inc dba Care for Life	www.careforlife.com
	Prescription Solutions	www.rxsolutions.com
	RxWEST Pharmacy	www.rxwest.com
	Tel-Drug, Inc./CIGNA	www.teldrug.com
	Walgreens, Co.	www.walgreens.com

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H-120.949 Guidance for Physicians on Internet Prescribing

Our AMA provides the following guidance for physicians on the appropriate use of the Internet in prescribing medications:

(a) Criteria for an acceptable patient (clinical) encounter and follow-up: Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall: (i) obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided; (ii)have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s); (iii) as appropriate, follow up with the patient to assess the therapeutic outcome; (iv) maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and (v) include the electronic prescription information as part of the patient medical record. Exceptions to the above criteria exist in the following specific instances: treatment provided in consultation with another physician who has an ongoing professional relationship with the patient, and who has agreed to supervise the patient's treatment, including use of any prescribed medications; and on-call or cross-coverage situations.

(b) Licensure Physicians who prescribe medications via the Internet across state lines, without physically being located in the state(s) where the patient (clinical) encounter(s) occurs, must possess appropriate licensure in all jurisdictions where patients reside. An exception to this requirement is when the clinical encounter with the patient, as described in recommendation 1(a) above, occurs in the state where the physician is licensed and his or her practice is located, and the state where the patient resides allows electronic prescriptions from out-of-state prescribers.

(c) Security of patient information Physicians who prescribe via the Internet should transmit prescriptions over a secure network (i.e., provisions for password protection, encrypted electronic prescriptions, or other reliable authentication techniques [e.g., AMA Internet ID]) in order to protect patient privacy.

(d) Disclosure of identifying information on web sites Physicians who practice medicine via the Internet, including prescribing, should clearly disclose physician-identifying information on the web site, including (but not necessarily limited to) name, practice location (address and contact information), and all states in which

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licensure is held. Posting of actual physicians' license numbers (e.g., the DEA number) is unnecessary.

(e) Liability exposure Physicians should be aware that they may increase their liability exposure by prescribing medications to individuals solely through online interactions (e.g., online questionnaire or online consultation). (BOT Rep. 7, A-03; Reaffirmed: BOT Rep. 3, I-04)

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